



Issue No. 27 A quarterly bulletin to assist hospitals, nursing homes, and other device user facilities Summer 1999

FDA SENDS PUBLIC HEALTH NOTICE ABOUT IMPORTANT Y2K PLANNING INFORMATION

The Food and Drug Administration (FDA) recently notified hospital and healthcare facility administrators, risk managers, and biomedical/clinical engineers about the Year 2000 (Y2K) contingency planning (*FDA Public Health Notification: Important Y2K Planning Information, July 16, 1999*). This planning is important for medical devices that are computer controlled and date related. The notice also offered to assist them in their Y2K planning and to encourage prompt reporting of certain Y2K problems to the FDA MedWatch database. FDA believes that only a few types of devices have a potential to present a significant risk to patients as a result of a Y2K failure. Healthcare facilities are encouraged to assess their biomedical equipment and automated systems and to develop contingency plans as soon as possible.

Y2K Contingency Plan

Facilities must have a Y2K contingency plan to:

- address unforeseen events that might occur because of date-related problems with computer-controlled medical devices and other systems;
- assess the impact of non-compliant Y2K devices on their ability to provide care; and
- identify necessary actions to take if a medical device experiences an unexpected failure.

Information to Assist in Your Planning

The following information can assist your facility in planning for Y2K problems.

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- A list of computer-controlled medical devices considered potentially high risk for causing serious adverse events from the Federal Y2K Biomedical Equipment Clearing House site at:

<http://www.fda.gov/cdrh/yr2000/cdrh/phrds/pdf/PHRD-List.pdf>

- *Patient-Focused Y2K Contingency Planning Guide* from the Department of Veterans Affairs at:

<http://www.va.gov/year2000/>

- *The Year 2000 Medical Device Assessment Guidebook* from the Department of Veterans Affairs at:

<http://www.va.gov/year2000/mdguide.pdf>

Issues to Consider in Contingency Plans.

The following issues should be considered in contingency plans:

- the adverse impact of stockpiling medical devices which increases the potential for induced shortages and increased costs (also on drugs and biologics). See letter on page 3 for the results of a White House-sponsored meeting on this subject; and
- any computer systems that contain patient records and other significant data.

Federal Y2K Biomedical Equipment Clearinghouse

At FDA's request, manufacturers provided detailed information regarding the Y2K status of their biomedical equipment for inclusion in the Federal Y2K Biomedical Equipment Clearinghouse. This database was developed for the convenience of healthcare facilities and device users. The site contains two kinds of information for your use.

- Y2K Non-Compliant Products – Information on non-compliant products, as well as more detailed descriptions of how products will operate as a result of their uncorrected date problem*
- Y2K Compliant Products – Information on specific product models that are Y2K compliant*

MedWatch Reporting Database

Report serious adverse events to FDA's MedWatch Reporting Database.

Mandatory MedWatch Reports

What to Report. As with any device-related death or serious injury, facilities are required to report deaths to FDA and the manufacturer and serious injuries to the manufacturer only. Report these problems through your facility's Medical Device Reporting (MDR) procedures and identify the report as a Y2K problem.

Voluntary MedWatch Reports

What to Report. Any date-related problem that did not cause a death or serious injury but caused unexpected performance, e.g., a malfunction that could cause death or serious injury *if the problem recurred*. FDA encourages reporting any contradiction between device findings and those findings claimed by the manufacturer. Identify the report as a Y2K problem. Report by phone to 1-800-FDA-1088; by FAX using Form 3500 to 1-800-FDA-0178; by mail using Form 3500 to

MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20857-9787; or electronically at www.fda.gov/medwatch/index.html

Possible 1999 Problems

The Y2K or other date-related computer problems that could possibly occur on January 1, 2000 could affect some medical devices *at other times* during 1999 (e.g., 9/9/99) if programs that anticipate dates beyond January 1, 2000 are used.*

* FDA cannot guarantee the accuracy of the information provided by manufacturers.

Guidance for Industry and
the Clinical Community
**MDR Reporting Guidance for
Date-Related Problems Including Y2K**
Issued April 16, 1999
Available at <http://www.fda.gov/cdrh>
or by FAX at 1-800-899-0381 or 301-827-0111 (specify shelf number 2299).

LABOR AND DELIVERY BEDS: KEEPING NEWBORNS SAFE FROM FALLS*

by Sonia C. Swayze, R.N., M.A.

Immediately after delivery, a new mother was lying in a labor and delivery bed and cradling her infant son. The bed was in a semi-Fowler's position with the side rails up. The infant rolled over the side of the mattress, landed on the floor, and fractured his skull.

What went wrong?

Hospital personnel expect labor and delivery beds to safely accommodate the mother-infant bonding. However, these beds are not designed for use by both the mother and the infant without supervision, especially when the mother is tired or not fully alert. Side rails are not meant to be used as patient-restraining devices.

On this particular bed, the side rails are attached to the bed frame and remain horizontal when the bed is in a semi-Fowler's position. If a mother falls asleep while holding an infant, the baby could easily roll off the side of the mattress.



What precautions can you take?

Nurses and other staff members attending to the patient and infant are responsible for their safety. Follow these guidelines to avoid dangerous mishaps.

- If the mother is not fully awake or alert, encourage her to rest and place the baby in an infant isolette at the foot of the bed.
- If the mother is fully alert, place the infant isolette next to the bed so she can easily reach it.

- When not attending to the mother, put the bed in the lowest position with the side rails up.
- When the mother is alert and the infant is in bed with her, keep the side rails up.
- Make sure that the rails extend higher than the top of the mattress.
- If needed, use pillows for extra support.
- Keep the bed in its lowest position.
- Instruct the mother not to sleep while the infant is in bed with her.
- Review your institution's policies and procedures on the use of labor and delivery beds, as well as infant safety protocols.*

Sonia Swayze, R.N., is a nurse consultant in CDRH's Office of Surveillance and Biometrics.

*This article has been adapted from the May issue of *Nursing 99*



PRESIDENT'S COUNCIL ON YEAR 2000 CONVERSION

August 13, 1999

An Open Letter to the Health Care Community:

In the past several months, there has been an increasing level of interest within the health care sector about the readiness of the consumable medical and surgical supplies supply system for the Year 2000 (Y2K) date change.

The President's Council on Year 2000 Conversion convened in June a roundtable meeting of government agencies and industry organizations to learn more about preparations for the date change in this important area and to encourage greater cooperation across industry lines.

As was clear from the meeting, government agencies and organizations within the consumable medical and surgical supplies supply system (e.g., manufacturers, distributors, group purchasing organizations, hospitals, physicians, and other healthcare professionals) have been working cooperatively to prepare for the date change and its impact on the availability of consumable medical and surgical supplies. They have made substantial progress and both government and industry are confident that the supply system for consumable medical and surgical supplies should continue to function normally through January 1, 2000.

The roundtable discussions brought out the following key points:

- The supply system for consumable medical and surgical supplies routinely operates with a 30-day supply and has existing contingency arrangements for getting additional supplies to those who need them.
- Partners in the supply system have a proven track record of working together in emergency situations. The supply system has responded to disruptions from severe weather, natural disasters, and other unusual occurrences without serious or noticeable effects on health care services.
- Government agencies and organizations within the supply system that manufacture, distribute, purchase and provide consumable medical and surgical supplies are working together to enhance contingency planning for Y2K-specific issues to ensure normal availability of consumable medical and surgical supplies into the Year 2000 and beyond.
- Purchasers (e.g., hospitals, laboratories, physicians, group purchasing organizations, consumers) of consumable medical and surgical supplies are strongly advised to maintain normal ordering patterns throughout 1999 and into the Year 2000.
- Basing orders on actual need and historical use is the best way to avoid shortages at the beginning of the Year 2000. If some purchasers acquire more stock than they normally require, the system could lose the flexibility to respond to specific needs and shortages that may occur.
- To assure supply continuity as the Year 2000 approaches, members of the supply system should continue to communicate with each other about their needs, capabilities, and Y2K preparedness.
- Users of consumable medical and/or surgical supplies (e.g., glucose test strips, syringes) with questions about supply availability should speak with their local supplier.

We encourage you to share this information with your members and others in your organization.

Sincerely,

John A. Koskinen
Chair
President's Council on Year 2000 Conversion

Kevin Thurm
Deputy Secretary
Department of Health and Human Services

HOW TO AVOID INJURIES FROM LIQUID CHEMICAL DISINFECTANTS*

By Sharon F. Dillard, ARRT(N), CNMT, MS

While removing a surgical instrument from a container of glutaraldehyde-based disinfectant, a nurse accidentally dropped an instrument back into the solution. The disinfectant splashed under her glasses and into her eyes. Although the nurse's eyes were irrigated for 15 minutes, she developed corneal keratitis.

What went wrong?

In the above scenario, the nurse was not wearing personal protective equipment as recommended by the disinfectant manufacturer. Liquid chemical disinfectant/sterilants (LCD/S) and their fumes are dangerous and require careful handling according to the manufacturer's instructions for use and Occupational Safety and Health Administration (OSHA) guidelines.

What precautions should be taken?

- Do not take shortcuts. When working with LCD/S, always use appropriate personal protective equipment such as:
 - splashproof goggles,
 - full face shields,
 - gloves impervious to LCD/S,
 - aprons, and
 - gowns.
- Use a ventilator designed for use with chemicals (as needed).
- Review the Material Safety and Data Sheets (MSDS) for the LCD/S being used; they specify the proper procedures for working with these chemicals.
- If your facility does not have MSDS, obtain them from the product manufacturer or on the Internet at <http://www.cdc.gov/niosh/npg.html>.
- Make sure that emergency care procedures are displayed in areas where LCD/S are used and stored.

If you have questions regarding the safe handling or use of these products, contact the manufacturer and refer to professional practice guidelines. A valuable document entitled *Safe Use and Handling of Glutaraldehyde-Based Products in Health Care Facilities* is available by calling the Association for the Advancement of Medical Instrumentation at 703-525-4890, ext. 217.

As a front-line healthcare worker, you may be the first person to recognize a device safety problem. Reporting problems to MedWatch (1-800-FDA-1088) helps the Food and Drug Administration address device-related public health concerns. *

Sharon Dillard is a Senior Scientist in CDRH's Office of Surveillance and Biometrics.

*This article has been adapted from the July issue of *Nursing 99*

When a
device
goes
to market,
we know
everything
about its
safety.

Wrong.

1-800-FDA-1088



MEDWATCH

The FDA Medical Products
Reporting Program

If it's serious, we need to know.

HOW TO HANDLE FAILED DEVICES

EDITOR'S NOTE: Because the Food and Drug Administration continues to receive failed devices, we are reprinting the following letter from the September 1997 issue of the User Facility Reporting Bulletin (page 6).

**PLEASE
DO NOT SEND
FAILED DEVICES TO FDA**
Although it is important for FDA to learn of adverse incidents caused by medical devices, only a written report is necessary. We do NOT need to receive and inspect the device.

Dear Editor:

On page 3 of the Spring 1997 issue in heavy outline was an admonition from FDA to users "PLEASE DO NOT SEND FAILED DEVICES TO FDA." We can appreciate FDA's position in advising users that it is not appropriate nor necessarily safe to send failed devices to FDA, but it would be helpful for FDA to guide users who are obviously perplexed about how to proceed.

Users who experience adverse incidents potentially related to failed medical devices should:

1. Assure that the failed device is taken out of service immediately with all attachments, disposables and packaging and without changing any settings or configurations;
2. Assure that all sharps and/or potentially contaminated products are handled, packaged, stored and, if necessary, shipped safely;
3. Contact the appropriate authority within the facility (e.g., biomedical or clinical engineering, risk management, quality assurance, hospital legal counsel) to advise them of the incident and to seek their guidance concerning how to proceed;
4. If advised by the proper facility authority (and we highly advise cooperation as follows), contact the manufacturer(s) of the product to advise them of the incident and to seek their guidance concerning how to proceed;
5. Complete the MedWatch Form with the assistance of the appropriate authority within the facility and submit the form to FDA and/or the manufacturer as required by the mandatory device reporting requirements within the Safe Medical Devices Act.

It is important to understand that these steps help to:

- Assure that the failed product is not utilized on a second patient or used by another staff member;
- Assure that neither staff (including shipping and handling personnel on both the shipping and receiving sides) nor investigators are unnecessarily exposed to sharps or potentially contaminated material;
- Assure that the product (and serial and lot numbers via packaging) as it was in use can be inspected and tested to determine if accessories, control settings or a myriad of other factors may have contributed to the failure;
- Maintain the integrity of the facility's risk management program and litigation position and allow internal review of the situation by knowledgeable professionals;
- Assure that manufacturers are advised as soon as possible so that similar incidents in other facilities may be avoided;
- Assure that manufacturer expertise in determining causation and in assuring safety in handling and return packaging can be brought to bear; and
- Assure that an independent overseer (i.e., in this case, FDA) is made aware of the incident and can monitor the steps taken to determine causation and desirable steps to avoid the occurrence of similar incidents.

Facilities may wish to seek the counsel of an independent third party to determine and manage how to proceed.

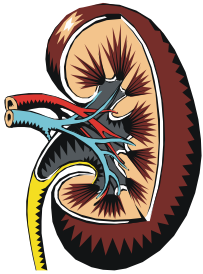
Our thanks for your willingness to consider our thoughts.

Gary H. Harding,
Director, Technical Services
Greener Pastures, Inc.

Alice L. Epstein
Risk Management Consultant to CAN HealthPro

PERITONEAL DIALYSTATE OVERFILL AND HUMAN FACTORS IMPLICATIONS*

By Marie H. Reid, RN, BSN, and Charles Sawyer, Ph.D.



The Food and Drug Administration (FDA) has received numerous reports of deaths and serious injuries from dialysate overfill by continuous cycling peritoneal dialysis (CCPD) machines (also known as peritoneal dialysis cyclers or PD cyclers). PD cyclers have been associated with incidents in which excessive fluid was introduced into a patient's intraperitoneal cavity, commonly referred to as "dialysate overfill." Nurses who perform CCPD or teach staff, patients, and family members how to use PD cyclers need to be aware of the dangers of peritoneal dialysate overfill.

Background

More than 250,000 patients in the United States have end stage renal disease (ESRD) and are using some type of dialysis therapy. Of these patients with ESRD, about 30,000 receive PD therapy. Other ESRD therapies are hemodialysis and kidney transplantation.

There are three types of PD: continuous ambulatory peritoneal dialysis (CAPD), continuous cycling peritoneal dialysis (CCPD), and intermittent peritoneal dialysis (IPD). PD is suited for patients who want more independence (self-care) or who have had contraindications to hemodialysis (e.g., problems with vascular access). Children are also more likely to be treated with CCPD, since they often have poor vascular access, have trouble adapting to the severe dietary constraints while awaiting transplantation, and are more likely to have contraindications to hemodialysis. As a consequence, they are often treated by lay users in a home environment.

Two Case Reports of Fatalities

The following case reports demonstrate how human factors contributed to the fatal outcomes. The conclusions are based on analyses of the two MedWatch incident reports, the cycler designs, and the manufacturers' investigations. Design and user training clearly contributed to the incidents.

Case 1 – Improper Control and Monitoring. An infant who underwent treatment with a PD cycler received an excessive amount of dialysate fluid in the intraperitoneal space and experienced a collapsed lung. Two or three interrelated errors may have been the cause.

- The administration tubing attached to the dialysis catheter remained unclamped which allowed free-flow of the PD priming solution.

- The home care provider, who was not medically trained, may have become confused and may have selected incorrect PD cycler actions.
- The control panel was positioned at knee level, making the monitoring of the device more difficult.

Case 2 – Improper Installation. While undergoing CCPD, an elderly patient experienced cardiovascular collapse because an excessive amount of fluid flowed into the intraperitoneal cavity. Because an occluder device either was installed incompletely or backwards, excessive dialysate bypassed the normal control mechanisms, entered the patient's abdominal cavity, and caused cardiovascular collapse when overfilled.

Patient Care Issues

Dialysate Overfill. Overfill is a serious complication and must be carefully monitored. If a patient (e.g., small children and handicapped adults) is unable to communicate, the care giver should closely monitor for clinical signs and symptoms such as:

- shortness of breath,
- decreased pulmonary function,
- abdominal discomfort,
- distension,
- pain, and
- possible abdominal wall herniation (e.g., umbilical or inguinal)

If overfill is suspected, the care giver should immediately stop the PD dialysate infusion and manually drain the patient's abdominal cavity using gravity flow before serious injury or death occurs.

Introduction of Air into the Intraperitoneal Cavity. The administration tubing connected to the PD catheter must be cleared of air before the infusion of dialysate. If this is not done, air will be delivered into the abdomen during the first PD cycle. Until it is absorbed, free air in the abdomen can cause severe hiccups and shoulder and abdominal pain.

Good Human Factors Engineering in Medical Device Design

Because device users are human, errors can occur while using machines regardless of how sophisticated or simple a medical device is. Unfortunately, this is true with expert medical practitioners as well as with lay users. Users can make errors such as omitting critical steps, performing incorrect or out-of-sequence control actions,

installing a component incorrectly, or misinterpreting an alarm. Insufficient warnings or prompts will worsen the situation; and if there are inadequate checks (e.g., interlocks) or alarms, errors may not be detected or mitigated.

Some design characteristics for care givers to consider when evaluating a device are:

- Displays and labels should be easy to view and to read at normal operating distances and angles.
- Displayed data should be adequate, timely, accessible, and easy to understand.
- Labels on the control panel should make it easy to associate related controls and displays.
- Controls and keys should be easy to identify and activate, and functions should be obvious.
- Installation and operating steps should be straightforward and easy to remember.
- Sufficient and timely warnings, alerts, and alarms should be prominently displayed.
- Safety features such as redundant steps should be used where feasible.

Some desirable characteristics of user instructions are:

- Operating instructions are included in the labeling.
- Operating procedures are divided into clear, distinct steps.
- The language is easy to understand by the user population.
- Warnings are placed early in the text as well as adjacent to related steps.
- Important information is clearly identified and easy to locate.
- Critical terms and warnings are highlighted to capture the user's attention.

Summary

Good design is critical to the safe operation of any medical device. Although users of a device often receive training, this may not be enough to guarantee its safe operation. Safety also depends on how easy or difficult a machine is to use. This is determined by the user-interface design of both hardware and software. If a medical device and its user instructions are not straightforward and logical to use, the likelihood of errors could be substantial.



It is important for the medical community to reinforce patient-safety by evaluating user-interface design and instructional manuals when purchasing equipment. The result will be fewer incidents and less time required in user training.

FDA and other organizations are very involved in human factors issues and device design. For example, FDA now requires manufacturers to consider the user when designing medical equipment; it recently issued a guidance document describing human factor (HF) problems and the HF design process (available on the Internet at <http://www.fda.gov/cdrh/humfac/1497.html>). The Association for Advancement of Medical Instrumentation has also published guidelines, and the American Medical Association's National Patient Safety Foundation has selected reduction of medical errors as their mission.*

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*This article has been adapted from the April-June 1999 issue of *International Journal of Trauma Nursing*, vol. 5, no. 2, pp. 68-71.

User Facility Reporting Bulletin

FDA produces the *User Facility Reporting Bulletin* quarterly to assist hospitals, nursing homes and other medical device user facilities in complying with their statutory reporting requirements under the Safe Medical Devices Act of 1990, the Medical Device Amendments of 1992, and the Food and Drug Administration Modernization Act of 1997.

The *Bulletin's* contents may be freely reproduced. Comments should be sent to the Editor.

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